REMARKS

A. Summary of Examiner Interview

Applicant thanks Examiner MacNeill for conducting a telephonic interview with Applicant's representative, Mark Garrett, on June 7, 2007. The rejections of independent claims 1, 65, and 67 were discussed. No agreement was reached.

B. The Anticipation Rejection Based on Aebischer Is Overcome

Claims 1, 7, 11, 13, 21, 24, 27, 28, and 65 stand rejected as being anticipated over US 5,487,739 to Aebischer. Applicant has amended independent claim 1 to distinguish Aebischer. The rejection is overcome.

1. Claim 1

The Office contends that "another direction" recited in examined claim 1 is not a different direction from the claimed "a direction." Action at 6. The Office's interpretation of "another" contravenes the plain language of the claim, but in an effort to expedite prosecution, Applicant has amended claim 1 to recite a first direction and a second direction that is different from the first direction. Aebischer discloses percutaneously introducing a guidewire (102) in a direction through an introducer (guidance needle 100), but does not teach or suggest advancing guidewire 102 in a **different direction beyond the distal end of guidance needle 100**. This is clear from the description in Aebischer, which states that the distal ends of the guidance needle 100 and guidewire 102 both are placed in essentially the same location: either "at or proximate the treatment site 12'" (col. 9, lines 30-35; col. 10, lines 6-10). This is also clear from FIG. 2B of Aebischer. To the extent that FIG. 2B shows guidewire 102 as having extended beyond the distal end of guidance needle 100, the two are **aligned**, and it is clear that guidewire 102 was not advanced **in a different direction** beyond the distal end of guidance needle 100. For this reason,

the anticipation rejection of independent claim 1 is overcome and should be withdrawn. Claims 7, 11, 13, 21, 24, 27, and 28 depend from claim 1 and are novel over Aebischer for at least the same reason as claim 1.

Furthermore, some of the dependent claims are novel over Aebischer for additional reasons.

Dependent claim 11 recites that a cross section taken along the device has a shape that is non-circular. The Office points to FIG. 3A and tether 82, but tether 82 is not cannula 20 (which the Office asserts qualifies as the claimed "device"), nor is tether 82 introduced over a guidewire as recited in independent claim 1. The rejection of dependent claim 11 should be withdrawn for this additional reason.

Dependent claim 13 recites delivering medication to an intracranial subarachnoid space. The Office asserts that pellet 80A is delivered to an intracranial subarachnoid space. This is not correct. There is no mention of intracranial subarachnoid space in Aebischer. Furthermore, the only discussion of the cranium generally pertains to the method discussed with respect to FIGS. 1A-1G, which involves a stereotactic frame and a surgical passageway through the skull (*see* these figures and col. 7, lines 29-31), not a percutaneous introduction of a guidewire or a device, as claimed. *See also* FIG. 4 of Aebischer. The rejection of dependent claim 13 should be withdrawn for these additional reasons.

Dependent claim 21 recites introducing a penetration apparatus through the first passageway of the device, the penetration apparatus including **an outer sleeve element and an inner puncture element**, the outer sleeve element and the inner puncture element being slidably coupled together; and puncturing the pia matter using the penetration apparatus. The Office points to guidance needle 100 and distal end 100B of guidance needle 100 as if they satisfy the

claimed outer and inner elements that are slidably coupled together. They do not because they both refer to the needle and nothing else. *See, e.g.,* col. 10, lines 12-17 (100B is the distal end of needle 100). The rejection of dependent claim 21 should be withdrawn for this additional reason.

Dependent claim 24 recites monitoring the position of the device for a period of time using magnetic resonance imaging, fluoroscopy, endoscopy, computed tomography, thermal imaging, sonography, or any combination of these. The Office points to the first full paragraph of column 5 and asserts "the position of the device is monitored via radio-opaque material." This is not correct. The cited paragraph discusses monitoring the "**vehicle**" that is inserted through the cannula. It does not discuss monitoring the cannula (which the Office relies on as the claimed device) for a period of time, as claimed. The rejection of dependent claim 24 should be withdrawn for this additional reason.

2. Claim 65

Independent claim 65 has not been amended to distinguish Aebischer because no amendment is necessary. It recites, in relevant part, introducing a penetration apparatus through the first passageway of the device, the penetration apparatus including **an outer sleeve element and an inner puncture element**, the outer sleeve element and the inner puncture element being slidably coupled together; and puncturing the pia matter using the penetration apparatus. The Office points to guidance needle 100 and distal end 100B of guidance needle 100 as if they satisfy the claimed outer and inner elements that are slidably coupled together. They do not because they both refer to the needle and nothing else. *See, e.g.,* col. 10, lines 12-17 (100B is the distal end of needle 100). Accordingly, the anticipation rejection of independent claim 65 is overcome and should be withdrawn.

C. The Obviousness Rejection of Claims 2 and 22 Is Overcome

Claims 2 and 22 stand rejected as being obvious over Aebischer in view of US 6,328,694 to Michaeli. Claims 2 and 22 depend from claim 1 and are novel over Aebischer for at least the same reason as claim 1. Michaeli does not cure Aebischer's deficiency. Therefore, claims 2 and 22 are nonobvious over the asserted combination, and the rejection should be withdrawn. Furthermore, Michaeli fails to disclose or suggest creating a lesion in the brain, as recited in claim 22. The Office does not address this limitation. Thus, claim 22 is patentable over the asserted combination for this additional reason.

D. The Obviousness Rejection of Claim 3 Is Overcome

Claim 3 stands rejected as being obvious over Aebischer. The rejection is overcome and should be withdrawn for the same reason as the rejection of independent claim 1 based on Aebischer.

E. The Obviousness Rejection of Claim 8 Is Overcome

Claim 8 stands rejected as being obvious over Aebischer in view of US 6,004,262 to Putz. Claim 8 depends from claim 1 and is novel over Aebischer for at least the same reason as claim 1. Putz does not cure Aebischer's deficiency. Therefore, claim 8 is nonobvious over the asserted combination, and the rejection should be withdrawn.

F. The Obviousness Rejection of Claims 25, 26, and 67 Is Overcome

1. Claims 25 and 26

Claims 25 and 26 stand rejected as being obvious over Aebischer in view of US 6,330,466 to Hofmann. Claims 25 and 26 depend from claim 1 and are novel over Aebischer for at least the same reason as claim 1. Hofmann does not cure Aebischer's deficiency. Therefore,

claims 25 and 26 are nonobvious over the asserted combination, and the rejection should be withdrawn.

2. Claim 67

Independent claim 67 stands rejected as being obvious over Aebischer in view of Hofmann. Claim 67 has been amended to further distinguish the asserted combination, and now recites, in relevant part, placing the electrode **on or in** brain tissue. The Office admits that Aebischer fails to teach "the use of an electrode placed near the brain[,]" but asserts that Hofmann cures this deficiency and that it would have been obvious "to use the insertion procedure of Aebischer in order to insert the electrode of Hofmann near the brain tissue in order to provide treatment to a patient." Action at p. 7. However, Hofmann concerns stereotactic neurosurgery, which generally involves non-percutaneous access to the brain, and there is no suggestion in Hofmann of gaining access to the brain percutaneously. Furthermore, the brain access disclosed by Aebischer appears in FIG. 4 as access achieved via cutting through skull bone. This also appears to be true for the method described in conjunction with FIGS. 1A-1G. *See* col. 7, lines 29-31 ("Generally, the method involves **surgically exposing** an insertion site **10** located above a desired, pre-determined treatment site **12**.") (emphasis added); *see also* col. 7, lines 45-47 (specifying that insertion location is determined using a stereotactic assembly).

While Aebischer does disclose percutaneous introduction in FIG. 2J (col. 9, lines 25-30), there is no disclosure or suggestion of navigating any of the subarachnoid space beyond the disclosed treatment site 12'. That is simply not the purpose of Aebischer, and the Office has failed to point to any evidence or logical reasoning why one of ordinary skill in the art would modify Aebischer as suggested. Moreover, the fact that Aebischer shows brain access through craniotomy actually teaches away from the subject matter of claim 67.

For these reasons, the rejection is overcome and should be withdrawn.

G. Conclusion

The pending claims are in condition for allowance. The Examiner is invited to contact the undersigned attorney at (512) 536-3031 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

/Mark T. Garrett/

Mark T. Garrett
Reg. No. 44,699
Attorney for Applicant

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201
(512) 536-4598 (facsimile)
Date: June 19, 2007